IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
WACO DIVISION

CHILDREN'S HEALTH DEFENSE, DEBORAH L. ELSE, SACHA DIETRICH, AIMEE VILLELLA MCBRIDE, JONATHAN SHOUR, and REBECCA SHOUR, *Plaintiffs*,	§	**Case No. 6:22-CV-00093-ADA**
v.	§	
FOOD & DRUG ADMINISTRATION and ROBERT M. CALIFF, *Defendants*.	§	

ORDER GRANTING DEFENDANTS' MOTION TO DISMISS

Before the Court is Defendants Food & Drug Administration ("FDA") and FDA Commissioner Robert M. Califf's Motion to Dismiss for Lack of Subject-Matter Jurisdiction and Failure to State a Claim filed on July 29, 2022. ECF No. 29. Plaintiffs Children's Health Defense ("CHD"), Deborah L. Else, Sacha Dietrich, Aimee Villella McBride, Jonathan Shour, and Rebecca Shour filed a response to Defendants' Motion on August 26, 2022. ECF No. 30. Defendants filed a reply in support of their Motion on September 16, 2022. ECF No. 31. The Court held a hearing on the Motion on November 18, 2022. ECF No. 33.

After considering the parties' briefing, the arguments at the hearing, the relevant facts, and the applicable laws, the Court **GRANTS** Defendants' Motion to Dismiss for Lack of Subject-Matter Jurisdiction. The Court concludes that Plaintiffs lack standing to sue. The Court does not reach the other issues in Defendants' Motion.

I. BACKGROUND

On March 27, 2020, the Secretary of the Health and Human Services determined that "circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic." Emergency Use Authorization Declaration, 85 Fed. Reg. 18250, 18250−51 (Apr. 1, 2020). In December 2020, FDA issued emergency use authorizations (EUAs) for the COVID-19 vaccines produced by Pfizer-BioNTech and ModernaTX, Inc. Authorizations of Emergency Use of Two Biological Products During the COVID-19 Pandemic, 86 Fed. Reg. 5200, 5201 (Jan. 19, 2021). On October 29, 2021, FDA revised the EUA to authorize administration of the Pfizer vaccine to children ages five to eleven. ECF No. 26-1 at 106 n.12. On June 17, 2022, the FDA further revised the EUA to authorize the administration of the Pfizer vaccine to children ages 6 months to 4 years. *Id.* at 107. The FDA states on its website that "there is an option to accept or refuse receiving the vaccine." ECF No. 29 at 3. The FDA also states that "[s]hould you decide for your child not to receive it, it will not change your child's standard medical care." *Id.*

In May 2021, CHD filed a petition with the FDA asking the agency to revoke the existing EUAs for the COVID-19 vaccine. *Id.* at 3−4. The FDA denied this petition. *Id.* at 4. On January 24, 2022, Plaintiffs filed this action against Defendants. ECF No. 1. In its first Complaint, Plaintiffs alleged that the FDA failed to comply with the Administrative Procedures Act (APA) when it approved the COVID-19 vaccine for children. *Id.* ¶ 18. On April 25, 2022, Defendants filed their first Motion to Dismiss Plaintiffs' Complaint for lack of jurisdiction and for failure to state a claim. ECF No. 18. Defendants argued that this Court lacked subject-matter jurisdiction because no Plaintiff has standing to sue and sovereign immunity bars Plaintiffs' cause of action. *Id.* at 6. In the alternative, Defendants argued that the case should be dismissed for failure to plausibly state a claim for relief. *Id.* at 15. The Court held a hearing on Defendants' first Motion to Dismiss on May

17, 2022. ECF No. 25. At the hearing, the Court granted Defendants' Motion to Dismiss for lack of subject matter jurisdiction without prejudice. *Id.* Based on Plaintiffs' first Complaint, the Court found that Plaintiffs lacked standing to sue and did not rule on the other grounds for Defendants' Motion to Dismiss. The Court granted Plaintiffs leave to amend their complaint.

Plaintiffs filed their Amended Complaint on July 1, 2022. ECF No. 26. In their Amended Complaint, Plaintiffs reallege that the FDA failed to comply with the APA when it approved the COVID-19 vaccine for children. *Id.* ¶¶ 212−46. The individual Plaintiffs, Deborah L. Else, Sacha Dietrich, Aimee Villella McBride, Jonathan Shour, and Rebecca Shour, claim that they are in imminent risk of immediate harm because of the authorization and advertising of the COVID-19 vaccine for their children. *Id.* ¶¶ 9−12. Some of the individual Plaintiffs claim that they are at risk because their children may be coerced to receive the vaccine, may be forced to take the vaccine due to impending mandates, may receive the vaccine without parental consent, or may suffer adverse reactions should they be given the vaccine. *Id.* ¶¶ 10−11. Plaintiffs claim that "Defendants' arbitrary and capricious actions warrant a stay, a vacatur and remand." *Id.* ¶ 247. Plaintiffs also seek a declaratory judgment that: "Defendants cannot use the emergency authorization statute to mislabel drugs as vaccines, mislabel drugs that have not been thoroughly tested as safe and effective, mislabel drugs as permitted to be compelled without informed consent, and to mislabel drugs to children that result in mandates being issued concerning those children's access to basic services, including medical and educational services." *Id.* ¶ 249. Plaintiffs further ask the Court to order the FDA to use "the regular biologic licensure process that incorporates citizen participation." *Id.*

Defendants filed the present Motion in response to Plaintiffs' Amended Complaint. ECF No. 29. Defendants argue that Plaintiffs' Amended Complaint should be dismissed because the

Court lacks subject-matter jurisdiction over Plaintiffs' claims. *Id.* at 5. Defendants argue that no Plaintiff has standing to sue. *Id.* at 6. Defendants argue that the individual Plaintiffs lack actual imminent risk of injury sufficient to meet the injury-in-fact requirement for standing. *Id.* at 6. Defendants argue that CHD lacks organizational and associational standing because none of its members possess standing. *Id.* at 11. Defendants further argue that if the Plaintiffs have standing, sovereign immunity bars the suit. *Id.* at 5−6. Lastly, Defendants argue that even if this Court has subject-matter jurisdiction over the claim, Plaintiffs' Amended Complaint should be dismissed for failure to plausibly state a claim for relief. *Id.* at 16. The Court held a hearing on this motion on November 18, 2022. ECF No. 33. The Court took Defendants' Motion under advisement. *Id.*

II. LEGAL STANDARD

The law of standing is built around "the idea of separation of powers." *TransUnion LLC v. Ramirez*, 141 S.Ct. 2190, 2203 (2021). For a federal court to have subject-matter jurisdiction, the plaintiff must present a case or controversy under Article III of the Constitution. *Id.* In other words, the plaintiff must have standing. *Id.* To establish standing, the plaintiff must show: (1) the plaintiff has suffered an injury in fact, (2) there is a casual connection between the injury and the defendant's conduct, and (3) the plaintiff's injury would likely be redressed through judicial relief. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560−61 (1992).

"Under Article III, federal courts do not adjudicate hypothetical or abstract disputes." *TransUnion*, 141 S.Ct. at 2203. The plaintiff must show an "injury in fact that is concrete, particularized and actual or imminent." *Id.* For an injury to be "concrete," it must be "real, and not abstract." *Id.* at 2204. An injury-in-fact cannot be "'conjectural' or 'hypothetical.'" *Susan B. Anthony List v. Driehaus,* 573 U.S. 149, 158 (2014) (quoting *Lujan*, 504 U.S. at 560). When evaluating whether a harm is "concrete," courts consider "whether the asserted harm has a 'close relationship' to a harm traditionally recognized as providing a basis for a lawsuit in American

courts—such as physical harm, monetary harm, or various intangible harms." *TransUnion*, 141 S.Ct. at 2204. Mental angst from an alleged violation that impacts the public at large is typically not considered a concrete harm. *See Hein v. Freedom From Religion Foundation, Inc.*, 551 U.S. 587, 633 (2007) (Scalia, J., concurring) (concluding that a taxpayer's mental angst is merely a generalized grievance and is not an injury-in-fact); *Lujan*, 504 U.S. at 573−574 (concluding that a "generally available grievance about the government" is not sufficient for standing). The Supreme Court has held that "the psychological consequence presumably produced by observation of conduct with which one disagrees" is "not injury sufficient to confer standing under Art. III." *Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc.*, 454 U.S. 464, 485 (1982). The Sixth Circuit has held that "the purported indignity of receiving a letter" is a "psychic injury [that] falls well short of a concrete harm needed to establish Article III standing." *Glennborough Homeowners Ass'n v. U.S. Postal Serv.*, 21 F.4th 410, 415 (6th Cir. 2021).

For an injury-in-fact to be "imminent," "there must be at least a 'substantial risk' that the injury will occur." *Stringer v. Whitley*, 942 F.3d 715, 721 (5th Cir. 2019) (quoting *Susan B. Anthony List*, 573 U.S. at 158). "[A]llegations of possible future injury are not sufficient." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013). An injury is not "imminent" where "the plaintiff alleges only an injury at some indefinite future time, and the acts necessary to make the injury happen are at least partly within the plaintiff's own control." *Lujan*, 504 U.S. at 564 n.2.

An organization can have associational or organizational standing. To have associational standing, the organization must show: (1) that its members independently possess Article III standing, (2) "the interests the association seeks to protect are germane to the purpose of the organization," and (3) the claim and the relief requested does not require participation of the individual members. *Ctr. for Biological Diversity v. U.S. EPA*, 937 F.3d 533, 536 (5th Cir. 2019).

To have organizational standing, the organization must show a "concrete and demonstrable injury to [its] activities—with the consequent drain on [its] resources," not "simply a setback to [its] abstract social interests." *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982). "Not every diversion of resources to counteract the defendant's conduct, however, establishes an injury in fact." *NAACP v. City of Kyle*, 626 F.3d 233, 238 (5th Cir. 2010). "For example, the mere fact that an organization redirects some of its resources to litigation and legal counseling in response to actions or inactions of another party is insufficient to impart standing upon the organization." *Louisiana ACORN Fair Housing v. LeBlanc*, 211 F.3d 298, 305 (5th Cir. 2000) (quotations omitted).

With respect to procedural injuries, the Supreme Court has "consistently held that a plaintiff raising only a generally available grievance about government—claiming only harm to his and every citizen's interest in proper application of the Constitution and laws, and seeking relief that no more directly and tangibly benefits him that it does the public at large—does not state an Article III case or controversy." *Lujan*, 504 U.S. at 573−574. Further, "Congress's creation of a statutory prohibition or obligation and a cause of action does not relieve courts of their responsibility to independently decide whether a plaintiff has suffered a concrete harm." *TransUnion*, 141 S.Ct. at 2205. "[A] bare procedural violation, divorced from any concrete harm" does not satisfy the injury-in-fact requirement of Article III. *Spokeo, Inc. v. Robins*, 578 U.S. 330, 341 (2016).

The plaintiff has the burden of showing that it has standing. *TransUnion*, 141 S.Ct. at 2207. When considering standing at the motion-to-dismiss stage, "general factual allegations of injury resulting from the defendant's conduct may suffice" and the court presumes that "general

allegations embrace those specific facts that are necessary to support the claim." *Lujan*, 504 U.S. at 561.

III. ANALYSIS

The Court first considers whether it has subject-matter jurisdiction over this case. Defendants argue that both the individual Plaintiffs and CHD lack standing to sue. The Court considers whether each group of Plaintiffs has standing below.

A. *The Individual Plaintiffs Lack Standing to Sue*

Defendants argue that the individual Plaintiffs lack standing to sue because they have not suffered an injury in fact. ECF No. 29 at 6. The individual Plaintiffs have alleged the following injuries: (1) imminent risk of harm from the vaccine EUAs and (2) harm from vaccine advertising and loss of confidence in the FDA. The Court considers whether either of the individual Plaintiffs' alleged injuries meet the injury-in-fact requirement below.

1. Imminent Risk of Harm from the Vaccine EUAs

With respect to the individual Plaintiffs' allegation of harm from the vaccine EUAs, Defendants argue that Plaintiffs fail to allege a "substantial risk that the injury will occur." *Id.* at 6–7 (quoting *Stringer*, 942 F.3d at 721). Defendants argue that the FDA does not require children, or the public at large, to receive the vaccine. *Id.* at 7. Defendants argue that the individual Plaintiffs allege "an injury at some indefinite future time, and the acts necessary to make the injury happen are at least partly within the plaintiff's own control." *Id.* (quoting *Lujan*, 504 at 564 n.2). Defendants further argue that the individual Plaintiffs do not plead an imminent injury from any particular source. *Id.* at 8.

For the individual Plaintiffs in Texas, Deborah Else and Sacha Dietrich, Defendants point out that Texas law permits parents to consent or not to consent to receiving the vaccine. *Id.* (citing Tex. Fam. Code. § 151.001(6)). While Else and Dietrich fear that another adult may authorize

immunization of their children against their wishes, Defendants argue that Texas law prohibits this possibility. *Id.* Defendants further argue that Else and Dietrich's alleged imminent risk of harm from social pressure and impending mandates does not meet the injury-in-fact requirement. *Id.* Defendants point out that the Governor of Texas has prohibited any entity of Texas from requiring individuals to receive the vaccine. *Id.* (citing Executive Order GA-40 (Oct. 11, 2021)). With respect to the allegation that children in Texas are being denied medical services, Defendants argue that the Amended Complaint fails to provide facts demonstrating that Else and Dietrich's children face an imminent risk that they will be denied medical treatment. *Id.* at 9. Defendants argue that this remote possibility of harm does not meet the injury in fact requirement. *Id.*

For the individual Plaintiff in Florida, Aimee Villella McBride, Defendants argue that McBride fails to allege an imminent risk of harm. *Id.* Defendants argue that because Florida law prohibits educational institutions from requiring the COVID-19 vaccine for any student, McBride does not face an imminent risk of impending mandates. *Id.* Finally, for the individual Plaintiffs in North Carolina, Jonathan and Rebecca Shour, Defendants also argue that the Shours fail to allege an imminent risk of harm. *Id.* Defendants argue that because North Carolina law prohibits a health care provider from administering the vaccine to children without written consent from a parent or guardian, there is no imminent risk of harm that the Shour children will be given the COVID-19 vaccine without their consent. *Id.* at 9−10. While the Shours claim that they face imminent risk of harm because they may be moved elsewhere in the country for work and that state may have a vaccine mandate, Defendants argue that this hypothetical harm is too speculative to meet the injury-in-fact requirement. *Id.* at 10.

In response, Plaintiffs argue that exposure to potentially harmful products can satisfy the injury-in-fact requirement. ECF No. 30 at 12 (citing *Baur v. Veneman*, 352 F.3d 625

(2d Cir. 2003)). Further, Plaintiffs argue that agency actions that create health-related uncertainty satisfy the injury-in-fact requirement. *Id.* (citing *New York Pub. Int. Rsch. Grp. v. Whitman*, 321 F.3d 316 (2d Cir. 2003)). Plaintiffs also argue that impairing parents' medical control over their children has been found to satisfy the injury-in-fact requirement. *Id.* (citing *Tummino v. Torti*, 603 F.Supp.2d 519 (E.D.N.Y. 2009)).

Additionally, Plaintiffs argue that all of the individual Plaintiffs have shown that they are directly threatened by the FDA's EUAs. Plaintiffs argue that the individual Plaintiffs' children "face the risk of expanding vaccine mandates, including those preventing them from receiving life-saving transplants and medical treatment." *Id.* at 13−14. And while the Governor of Texas has banned vaccine mandates by executive order, Plaintiffs claim that this "executive order has not prevented discriminatory and cruel treatment towards the unvaccinated—particularly children." *Id.* at 14. Plaintiffs also argue that the Shours are at risk from mandates around the country because the family may move to any state in the future due to Chaplain Shour's employment in the U.S. Navy. *Id.* Plaintiffs also claim that under Texas law, adults other than a child's parent can consent to vaccination. *Id.* Lastly, Plaintiffs argue that they have also been harmed because they can no longer rely on the FDA's representations in the future. *Id.* at 15.

The Court finds that the individual Plaintiffs have not suffered an injury in fact as a result of the vaccine EUAs. The individual Plaintiffs have failed to show that they face imminent harm due to the FDA's EUAs. The individual Plaintiffs merely allege a speculative threat of harm from vaccination by a non-parent or impending vaccine mandates. But this type of speculative harm is insufficient to meet the injury-in-fact requirement. None of the individual Plaintiffs meet their burden of showing that the risk of future harm is "imminent." To plead an imminent future harm, Plaintiffs must show that "there is a substantial risk that the injury will occur." *Stringer*, 942 F.3d

at 715. The individual Plaintiffs claim that there is a risk that someone will authorize a vaccine for their children sometime in the future. However, under at least Texas and Florida law, vaccination cannot be mandatory. Tex. Executive Order GA-40 (Oct. 11, 2021); Fla. Stat. § 381.00319. Further, under at least Texas and North Carolina law, individuals other than the child's parent are not permitted to vaccinate a child. Tex. Fam. Code § 32.101(b)–(c); N.C. Gen. Stat. § 90-21.5(a1). Because the applicable state laws prevent mandatory vaccination and vaccination without parental consent, the individual Plaintiffs have failed to allege a substantial risk that injury will occur.

Further, with respect to the Shours, Plaintiffs have alleged that the Shours are at risk because they may be subject to mandates in another state if the Navy requires the family to move. Plaintiffs allege that the Shour children may be discriminated against or ostracized from certain activities if they move to a state with a vaccine mandate. ECF No. 30 at 14. But here, Plaintiffs merely assert "allegations of possible future injury." *Clapper*, 568 U.S. at 409. Such allegations are insufficient to confer standing. *Id.* Plaintiff have failed to show that there is a substantial risk that the Shours will move to a state with a vaccination mandate that will require the Shour children to be vaccinated to participate in certain activities.

Many of the cases cited by Plaintiffs are distinguishable and nonbinding. In *Baur v. Veneman*, the plaintiff alleged a credible threat of harm from exposure to potentially unsafe food products. *Baur*, 352 F.3d at 641. In *Baur*, the plaintiff provided data showing that the threat of harm arising from the agency action. *Id.* at 629. The plaintiff's data was confirmed by the agency's research. *Id.* at 638−640. Further the threat of harm was directly tied to the agency action. *Id.* at 640. Here, the Court has found that the individual Plaintiffs have failed to allege a credible threat of harm. The individual Plaintiffs merely allege that there is a chance that their children may be vaccinated against without their consent. Further, even if this threat were credible, it would be the

direct result of independent third-party action, not the FDA's EUAs. Further, in *New York Public Interest Research Group v. Whitman*, the plaintiffs alleged that the EPA's failure to enforce the Clean Air Act caused health effects and uncertainty. 321 F.3d at 325. In *Whitman*, the court focused on the fact that the plaintiff's members lived near facilities that may be releasing excess pollutants, which presented specific personal and economic harms. *Id.* at 325−326. However, in that case, the individual Plaintiffs are not in any particular danger of exposure. The FDA's EUAs do not put the individual Plaintiffs at an imminent risk of exposure because parents are free to choose whether to consent to their children receiving the COVID-19 vaccine. The FDA has stated that "there is an option to accept or refuse receiving the vaccine." ECF No. 29 at 3. In *Tummino v. Torti*, the FDA's regulations *prohibited* parents from making a decision for their children's medical care. *Tummino*, 603 F.Supp.2d at 540 (explaining that under the challenged FDA action, parents are unable to legally obtain Plan B on behalf of their children). Here, the FDA, and relevant state laws, provide parents the choice of whether to consent to their children receiving the vaccines authorized by the FDA's EUAs.

For the foregoing reasons, the Court concludes that the individual Plaintiffs allegations that they are imminent risk of harm due to the FDA's EUAs fail to meet the injury-in-fact requirement under Article III.

2. Harm from Vaccine Advertising and Loss of Confidence in the FDA

With respect to the individual Plaintiffs' allegation of harm from vaccine advertising, Defendants argue that Plaintiffs "cursorily allege that their children have been exposed to so called 'pro vaccine messaging.'" ECF No. 29 at 6 n.2. Defendants argue that "'the purported indignity of receiving a' message with which one disagrees is 'a psychic injury [that] falls well short of a concrete harm needed to establish Article III standing.'" *Id.* (quoting *Glennborough Homeowners Ass'n*, 21 F.4th at 415). Defendants argue that the psychological toll of pro vaccine messaging has

"no 'close historical or common-law analogue for their asserted injury.'" ECF No. 31 at 3 (quoting *TransUnion*, 141 S.Ct. at 2204). Defendants claim that such psychological toll is not sufficient to confer standing. *Id.* With respect to Plaintiffs' allegations that they have suffered a loss of confidence in the FDA, Defendants argue that Plaintiffs have failed to allege a "real and immediate threat of future harm." *Id.* at 4 (quoting *Funeral Consumers All, Inc. v. Serv. Corp. Int'l*, 695 F.3d 330, 343 (5th Cir. 2012)). Defendants assert that no plaintiff has claimed that it will refrain from using an FDA-approved products in the future and no plaintiff has explained how court-ordered relief would redress this alleged injury. *Id.*

Plaintiffs argue that they have suffered an injury from the "false advertising of COVID-19 shots." ECF No. 30 at 1. Plaintiffs also allege that the EUAs and false advertising caused the individual Plaintiffs to have a "complete collapse of confidence in the FDA." *Id.* at 3. Plaintiffs claim that the "FDA's misrepresentations have led to continuous coercion, propaganda, and advertisements aimed directly at children, to which Plaintiffs' children are subjected daily." *Id.* at 13. The individual Plaintiffs allege that such advertisements "harras[es]" and "pressure[s]" the Plaintiffs' children. *Id.* Plaintiffs claim that "coercive pressures, false advertising, and propaganda aimed at young children" presents an injury. *Id.* at 14. Plaintiffs allege that due to the FDA's EUAs and allegedly false advertising, the individual Plaintiffs "are no longer able to rely on FDA representations now or in the future." *Id.* at 15.

The Court finds that the individual Plaintiffs have not suffered an injury in fact as a result of vaccine advertising. Plaintiffs have merely alleged a "psychological consequence" "produced by observation of conduct with which one disagrees." *Valley Forge*, 454 U.S. at 485. The Supreme Court has found such an injury is not sufficient to confer standing. *Id.* The Court finds that any injury suffered as a consequence of the vaccine advertising is not sufficient to confer standing

because it is not the type of harm that is "traditionally recognized as providing a basis for a lawsuit in American courts—such as physical harm, monetary harm, or various intangible harms." *TransUnion*, 141 S.Ct. at 2204.

As to Plaintiffs' allegations that it has suffered a harm due to its loss of confidence in the FDA, the Court also finds that this injury does not give rise to Article III standing. Because Plaintiffs have failed to allege that this loss of confidence will alter their purchasing decisions in the future, any loss of confidence that the individual Plaintiffs have suffered does not present a real and immediate risk of future harm. *See Funeral Consumers*, 695 F.3d at 342 (determining that the plaintiff lacked standing where there was no "real or immediate threat" that the plaintiff would purchase the allegedly overpriced product). Because the individual Plaintiffs have not alleged that the loss of confidence presents a real and immediate risk of harm, the allegation that Plaintiffs have suffered a loss of confidence in the FDA does not give Plaintiffs standing to sue.

For the foregoing reasons, the Court finds that the individual Plaintiffs lack standing to sue under Article III.

B. *CHD Lacks Standing to Sue*

Defendants argue that CHD lacks both associational standing and organizational standing. ECF No. 29 at 11. To have associational standing, the organization must show that its members independently possess Article III standing. *Ctr. for Biological Diversity*, 937 F.3d at 536. Because the Court has determined that the individual Plaintiffs, the only identified members of CHD, failed to show that they independently possess Article III standing, the Court finds that CHD lacks associational standing.

As for organizational standing, CHD must show a "concrete and demonstrable injury to [its] activities—with the consequent drain on [its] resources," not "simply a setback to [its] abstract social interests." *Havens Realty Corp.*, 455 U.S. at 379. Defendants argue that CHD merely alleges

a vague and conclusory claim that the FDA's conduct has caused a serious diversion of CHD's resources. ECF No. 29 at 11. Defendants argue that CHD has failed to show any specific projects that CHD had to put on hold to respond to the FDA's conduct. *Id.* at 12. Defendants argue that the actions taken by CHD in response to the FDA's conduct are routine activities for the organization, which exists to protect and promote the health and wellbeing of children. *Id*. Defendants point to Fifth Circuit law, which states that "an organization does not automatically suffer a cognizable injury in fact by diverting resources in response to a defendant's conduct." ECF No. 31 at 5 (quoting *El Paso Cnty. v. Trump*, 982 F.3d 332, 343 (5th Cir. 2020)). Further, Defendants point to Fifth Circuit law, which states that the organization must show that any diversion of resources "concretely and 'perceptibly impaired'" its "ability to carry out its purpose." *Id.* (quoting *City of Kyle*, 626 F.3d at 239).

In response, CHD argues that it has organizational standing based on the concrete and demonstrable injury that the organization's activities have suffered due to "a consequent drain on the organization's resources." ECF No. 30 at 5 (quoting *Havens Realty Corp.*, 455 U.S. at 378). CHD complains that the FDA's actions have required CHD to "undergo a complete revamping of its budgeted plans." *Id.* at 3. CHD argues that the diversion of its resources, on its own, is sufficient to meet the injury in fact requirement under Article III. *Id.* at 7. CHD argues that it diverted resources in response to the FDA's conduct by: (1) investigating the FDA's actions and conducting its own studies on the vaccines, (2) working with its members to deal with the coercion and pressure to vaccinate, and (3) publishing newsletters, online video news, and live commentary to educate the public on the FDA's alleged misinformation. *Id.* at 9.

With respect to CHD's claim for organizational standing, the Court finds that CHD has not alleged a drain on its resources due to the FDA's conduct that would give rise to standing. The

Fifth Circuit has stated that "[n]ot every diversion of resources to counteract the defendants conduct . . . establishes an injury in fact." *City of Kyle*, 626 F.3d at 238. In *City of Kyle*, the plaintiff organization claimed that its prelitigation studies and correspondence on the impact of the government conduct diverted the organization's resources. *Id.* However, the Fifth Circuit concluded that the plaintiff organization failed to explain how these activities "differ from the [organization's] routine lobbying activities." *Id.* The Fifth Circuit determined that the organization lacked standing because "Plaintiffs have not demonstrated that the diversion of resources here concretely and 'perceptibly impaired' the [organization's] ability to carry out its purpose." *Id.* at 239. Here, CHD has similarly failed to show how its efforts in response to the FDA's EUAs differ from its ordinary activities. Further, CHD has failed to show how the diversion of resources in response to the FDA's conduct has "concretely and 'perceptibly impaired'" CHD's ability to carry out its purpose. *Id.* Thus, the Court determines that CHD has failed to show that it has organizational standing based on the diversion of its resources in response to the FDA's conduct.

CHD also argues that it has standing to enforce the APA. *Id.* at 7. CHD argues that the APA creates standing for "a person suffering legal wrong because of agency action." *Id.* at 9 (quoting 5 U.S.C. § 702). In response, Defendants argue that a bare procedural violation does not give rise to Article III standing. ECF No. 29 at 12. Defendants argue that CHD has failed to show that its procedural injury is "concrete and particular, as opposed to an undifferentiated interest in the proper application of the law." *Id.* at 12−13 (quoting *Sierra Club v. Glickman*, 156 F.3d 606, 613 (5th Cir. 1998)).

With respect to CHD's claim to standing under the APA, the Court concludes that CHD's procedural injury is merely a generalized grievance. The Supreme Court has "consistently held that a plaintiff raising only a generally available grievance about government—claiming only harm

to his and every citizen's interest in proper application of the Constitution and laws, and seeking relief that no more directly and tangibly benefits him that it does the public at large—does not state an Article III case or controversy." *Lujan*, 504 U.S. at 573−574. The procedural harm allegedly suffered by CHD is not concrete and particularized to CHD—it is the same procedural harm suffered by the public at large. Thus, CHD's alleged procedural harms do not give rise to standing under Article III.

IV. CONCLUSION

For the foregoing reasons, the Court **GRANTS** Defendants' Motion to Dismiss for Lack of Subject-Matter Jurisdiction. The Court concludes that all Plaintiffs lack standing to sue. The Court does not rule on Defendants' Motion to Dismiss for Failure to State a Claim. This case is hereby **DISMISSED** with prejudice.

SIGNED this 12th day of January, 2023.

ALAN D ALBRIGHT
UNITED STATES DISTRICT JUDGE